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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,755	11/15/2001	Lawrence M. Boyd	4002-2729	8631

7590

03/09/2004

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EXAMINER

COMSTOCK, DAVID C

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/869,755

Applicant(s)

BOYD ET AL.

Examiner

David Comstock

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 35-37 is/are allowed.  
6) ☒ Claim(s) 1-34 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre (4,950,296) in view of Brosnahan, III (5,645,598; cited by applicant).

McIntyre discloses a spacer 10 comprising an elongated body 12 and an opening into a chamber or hole 18 that extends perpendicularly to the longitudinal axis of the body (see Figs. 1 and 2 and col. 2, lines 47-52). The body defines two arms between the chamber and the two ends 14 and 16, respectively. The body is formed from the diaphysis of a long bone, i.e., the shaft of the femur (see col. 2, lines 53-58).

Osteogenic material 22 is packed into the spacer (see col. 2, lines 44-46; col. 2, line 61 - col. 3, line 4; and col. 3, line 28-36). McIntyre does not disclose the concave surfaces.

Brosnahan discloses providing a fusion device 10 with concave surfaces 48,50 to allow the fusion device to be nested with another fusion device and allow the use of taller fusion devices for correct anatomical positioning (see Fig. 14 and col. 5, lines 55-62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the spacer of McIntyre with concave surfaces, in view of Brosnahan, III, in order to allow the fusion device to be nested with another fusion device and allow the use of taller fusion devices for correct anatomical positioning. It is

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noted that positioning the concave surfaces such that they form concave ends on the arms would have been obvious since it has been held that mere relocation of features of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Brosnahan also discloses providing the fusion device with a tool engaging end 32 to allow the device to be inserted with a tool and to improve the convenience of the procedure (see col. 5, lines 8-12). It would have been further obvious to provide the spacer of McIntyre with a tool engaging portion, also in view of Brosnahan, III, in order to allow the spacer to be inserted with a tool and to improve the convenience of the procedure. With regard to claim 6, it is noted that the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight. With regard to claim 7, it also would have been obvious to provide the spacer of McIntyre with threading, in view of Brosnahan, III, in order to prevent motion and provide secure attachment to the vertebrae (see Brosnahan, III, col. 4, lines 44-51). With regard to claims 11-14, it would have been further obvious to one having ordinary skill in the art at the time the invention was made to use recombinant human protein comprising BMP-2 or to use any of a number of known osteogenic materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

***Response to Arguments***

Applicant's arguments regarding claims 1-34, filed 18 December 2003, have been fully considered but they are not persuasive.

In response to Applicant's argument that neither McIntyre nor Brosnahan, III disclose "arms," it is first noted that Brosnahan, III was not cited as showing any arms, but rather, Brosnahan, III was cited as a reference which teaches nesting of multiple spacers, as clearly set forth in the rejection. With regard to McIntyre, the arms disclosed therein have a structure like the arms of Applicant's invention. That is, the arms are merely that portion of the spacer defined between the ends and the chamber, as already set forth in the rejection. Thus, if Applicant's device has "arms" then so must the device of McIntyre.

Applicant's arguments, see page 9, lines 1-11, filed 18 December 2003, with respect to claim 35 have been fully considered and are persuasive. The rejection of claim 35 has been withdrawn.

***Allowable Subject Matter***

Claims 35-37 are allowed.

**Conclusion**

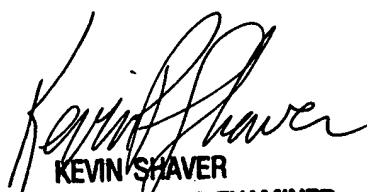
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.



D.C. Comstock  
05 March 2004



KEVIN SHAVER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700